

Package leaflet: Information for the patient

Cibinqo[®] Tablets 50 mg Cibinqo[®] Tablets 100 mg Cibinqo[®] Tablets 200 mg Abrocitinib

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In addition to this leaflet, your doctor will give you a patient card, which contains important safety information that you need to be aware of. Keep this patient card with you.

What is in this leaflet

1. What Cibinqo is and what it is used for
2. What you need to know before you take Cibinqo
3. How to take Cibinqo
4. Possible side effects
5. How to store Cibinqo
6. Contents of the pack and other information

1. What Cibinqo is and what it is used for

Cibinqo contains the active substance abrocitinib. It belongs to a group of medicines called Janus kinase inhibitors, which help to reduce inflammation. It works by reducing the activity of an enzyme in the body called 'Janus kinase', which is involved in inflammation.

Cibinqo is used to treat adults with moderate-to-severe atopic dermatitis, also known as atopic eczema. By reducing the activity of Janus kinase enzymes, Cibinqo lessens itching and inflammation of the skin. This in turn can reduce sleep disturbances and other consequences of atopic eczema such as anxiety or depression and improves overall quality of life.

2. What you need to know before you take Cibinqo

Do not take Cibinqo

- if you are allergic to abrocitinib or any of the other ingredients of this medicine (listed in section 6).
- if you have a serious infection ongoing, including tuberculosis.
- if you have severe liver problems.
- if you are pregnant or breast-feeding (see the "pregnancy, contraception, breast feeding and fertility" section).

Warnings and precautions

Talk to your doctor or pharmacist before and during treatment with Cibinqo if you:

- have an infection or if you often get infections. Tell your doctor if you get symptoms such as fever, wounds, feeling more tired than usual or dental problems as these can be signs of infection. Cibinqo can reduce your body's ability to fight infections and may make an existing infection worse or increase the chance of you getting a new infection. If you have diabetes or are aged 65 years or older you may have an increased chance of getting infections.
- have, or have had, tuberculosis or have been in close contact with someone with tuberculosis. Your doctor will test you for tuberculosis before starting Cibinqo and may retest during treatment.
- have ever had a herpes infection (shingles), because Cibinqo may allow it to come back. Tell your doctor if you get a painful skin rash with blisters as this can be a sign of shingles.
- have ever had hepatitis B or hepatitis C.
- have recently had or plan to have a vaccination (immunisation) - this is because certain vaccines (live vaccines) are not recommended while using Cibinqo.
- have previously had blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism) or have an increased risk for developing this (for example: if you had recent major surgery, if you use hormonal contraceptives/hormonal replacement therapy, if a coagulation defect is identified in you or your close relatives). Your doctor will discuss with you if Cibinqo is appropriate for you. Tell your doctor if you get sudden shortness of breath or difficulty breathing, chest pain or pain in upper back, swelling of the leg or arm, leg pain or tenderness, or redness or discoloration in the leg or arm as these can be signs of blood clots in the veins.
- have, or had heart problems because your doctor will discuss with you if Cibinqo is appropriate for you.
- have or have had cancer, smoke or have smoked in the past, because your doctor will discuss with you if Cibinqo is appropriate for you.
- Non-melanoma skin cancer has been observed in patients taking Cibinqo. Your doctor may recommend that you have regular skin examinations while taking Cibinqo. If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.

Additional monitoring tests

Your doctor will carry out blood tests before and during Cibinqo treatment and may adjust your treatment if necessary.

Children

This medicine is not approved for use in children below the age of 18 years because the safety and benefits of Cibinqo are not yet fully established.

Other medicines and Cibinqo

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist before taking Cibinqo if you are taking some of the medicines to treat:

- fungal infections (such as fluconazole), depression (such as fluoxetine or fluvoxamine), stroke (such as ticlopidine), as they may increase the side effects of Cibinqo.
- stomach acid reflux (such as antacids, famotidine or omeprazole), as they may reduce the amount of Cibinqo in your blood.
- depression (such as citalopram, clobazam or escitalopram), as Cibinqo may increase their effects.
- neurofibromatosis type I (such as selumetinib), as Cibinqo may increase its effects.
- heart failure (such as digoxin) or stroke (such as dabigatran), as Cibinqo may increase their effects.

- seizures (such as S-mephenytoin), as Cibinqo may increase its effects.
- stroke (such as clopidogrel), as Cibinqo may decrease its effects.
- asthma, rheumatoid arthritis, or atopic dermatitis (such as biologic antibody therapies, medicines that control the body's immune response such as ciclosporin, other Janus kinase inhibitors, such as baricitinib, upadacitinib), as they may increase the risk of side effects.

Your doctor can tell you to avoid using or stop taking Cibinqo if you are taking some of the medicines to treat:

- tuberculosis (such as rifampicin), seizures or fits (such as phenytoin), prostate cancer (such as apalutamide, enzalutamide), or HIV infection (such as efavirenz), as these may reduce how well Cibinqo works.

If any of the above apply to you or if you are not sure, talk to your doctor or pharmacist before taking Cibinqo.

Pregnancy, contraception, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Contraception in women

If you are a woman of childbearing potential, you should use an effective method of contraception during treatment with Cibinqo, and for at least one month after your last treatment dose. Your doctor can advise you on suitable methods of contraception.

Pregnancy

Do not use Cibinqo if you are pregnant, think you may be pregnant or are planning to have a baby since it can harm the developing baby. Tell your doctor right away if you become pregnant or think you might have become pregnant during treatment.

Breast feeding

Do not use Cibinqo while breast-feeding as it is not known if this medicine passes into breast milk and affects the baby. You and your doctor should decide if you will breast-feed or use this medicine.

Fertility

Cibinqo may cause temporary reduced fertility in woman of childbearing potential. This effect is reversible after stopping treatment.

Driving and using machines

Cibinqo has no effect on the ability to drive or use machines.

Cibinqo contains lactose monohydrate and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

Elderly

Patients aged 65 years and older may be at increased risk of infections, heart attack and some types of cancer. Your doctor may decide that Cibinqo is not suitable for you.

3. How to take Cibinqo

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Cibinqo is a tablet to be taken by mouth. It may be used with other eczema medicines that you apply on the skin or it may be used on its own.

The recommended starting dose is 100 mg or 200 mg once a day as prescribed by your doctor. Your doctor may increase or decrease your dose depending on how well the medicine is working. Some patients need a lower starting dose and your doctor may give you 100 mg once a day if you are 65 years of age or older, or if you have a certain medical history or medical condition. If you have moderate-to-severe kidney problems, or if you are prescribed certain other medicines the starting dose can be either 50 mg or 100 mg once a day. You will get a starting dose based on your need and medical history or medical condition, therefore you should always take this medicine exactly as your doctor has told you.

After starting treatment, your doctor can adjust the dose based on how well the medicine works and any side effect you get. If the medicine is working well, the dose may be reduced. Treatment may also be stopped temporarily or permanently if blood tests show low white blood cell or platelet counts.

If you have taken Cibinqo for 24 weeks and still show no improvement, your doctor may decide to permanently stop the treatment.

You should swallow your tablet whole with water. Do not split, crush or chew the tablet before swallowing as it may change how much medicine that gets into your body.

You can take the tablet either with or without food. If you feel sick (nausea) when taking this medicine, it may help to take it with food. To help you remember to take your medicine, it is suggested that you take it the same time every day.

If you take more Cibinqo than you should

If you take more Cibinqo than you should, contact your doctor. You may get some of the side effects described in section 4.

If you forget to take Cibinqo

- If you miss a dose, take it as soon as you remember, unless your next dose is due in less than 12 hours.
- If there is less than 12 hours before your next dose, just skip the missed dose and take your next usual dose when it is due.
- Do not take a double dose to make up for a forgotten tablet.

If you stop taking Cibinqo

You should not stop taking Cibinqo without discussing this with your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Talk to your doctor and get medical help straight away if you get any signs of:

- Shingles (herpes zoster), a painful skin rash with blisters and fever
- Blood clots in the lungs, legs or pelvis with symptoms such as a painful swollen leg, chest pain or shortness of breath

Other side effects

Very common (may affect more than 1 in 10 people)

- Feeling sick (nausea)

Common (may affect up to 1 in 10 people)

- Cold sores and other types of herpes simplex infections
- Vomiting
- Stomach pain
- Headache
- Dizziness
- Acne
- Increase in an enzyme called creatine phosphokinase, shown by blood test

Uncommon (may affect up to 1 in 100 people)

- Pneumonia (lung infection)
- Low platelet count shown by blood test
- Low white blood cell count shown by blood test
- High blood fat (cholesterol) shown by blood test (see section 2 Warnings and precautions)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Cibinqo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister foil after EXP. The expiry date refers to the last day of that month.

Please refer to outer carton for recommended storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cibinqo contains

- The active substance is abrocitinib.
Each 50 mg tablet contains 50 mg of abrocitinib.
Each 100 mg tablet contains 100 mg of abrocitinib.
Each 200 mg tablet contains 200 mg of abrocitinib.
- The other ingredients are:
Tablet core: microcrystalline cellulose (E460i), calcium hydrogen phosphate anhydrous (E341ii), sodium starch glycolate, magnesium stearate (E470b).
Film coat: hypromellose (E464), titanium dioxide (E171), lactose monohydrate, macrogol (E1521), triacetin (E1518), iron red oxide (E172) (see section 2 Cibinqo contains lactose and sodium).

What Cibinqo looks like and contents of the pack

Cibinqo Tablets 50 mg are pink, approximately 11 mm long and 5 mm wide oval tablets with “PFE” on one side and “ABR 50” on the other.

Cibinqo Tablets 100 mg are pink, approximately 9 mm in diameter round tablets with “PFE” on one side and “ABR 100” on the other.

Cibinqo Tablets 200 mg are pink, approximately 18 mm long and 8 mm wide oval tablets with “PFE” on one side and “ABR 200” on the other.

Cibinqo Tablets 50 mg

The tablets are provided in blisters. Each pack contains 28 tablets.

Cibinqo Tablets 100 mg

The tablets are provided in blisters. Each pack contains 28 tablets.

Cibinqo Tablets 200 mg

The tablets are provided in blisters. Each pack contains 28 tablets.

Pfizer Corporation Hong Kong Limited
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